

Odusote, Gloria

From: Odusote, Gloria
Sent: Tuesday, June 26, 2018 2:50 PM
To: 'Rugen, P. (Pamela)'
Subject: RE: P-17-0294 => Face to Face Meeting Request

Hi Pam,

The memo we sent you before our last meeting has the EPA policy regarding respiratory sensitization. I believe there was another memo that was sent to you for the SNUN case. The both state the same policy.

Best,
Gloria

From: Rugen, P. (Pamela) [mailto:Pamela.Rugen@akzonobel.com]
Sent: Tuesday, June 26, 2018 10:58 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: FW: P-17-0294 => Face to Face Meeting Request

Hi Gloria,

We are also would like to see any EPA policy concerning the respiratory sensitization issue.
Please send to me or let me know where the link is for this policy as business is pressuring me for it.
Thanks again,
Pam

From: Rugen, P. (Pamela)
Sent: Tuesday, June 26, 2018 9:31 AM
To: Gloria Odusote (odusote.gloria@epa.gov)
Cc: [REDACTED]
Subject: FW: P-17-0294 => Face to Face Meeting Request

Hi Gloria,

As stated below, combining the meetings will work for the Akzo Nobel team. Can you confirm that the meeting for the P-17-0294 PMN substance concerning respiratory sensitization will occur and at what time on July 19th?

Thank you,
Pam

From: Rugen, P. (Pamela)
Sent: Thursday, June 21, 2018 8:00 AM
To: Gloria Odusote (odusote.gloria@epa.gov)
Subject: FW: P-17-0294 => Face to Face Meeting Request

Hi Gloria,

Yes, combining the meetings would be perfect. Please send us a copy of the EPA policy on respiratory sensitization as we would like to review that prior to the meeting. Please send me details of the meeting times as I am not sure if time on the front end or back end of the current meeting will work for the EPA personnel.

Thank you,
Pam

Odusote, Gloria

From: Rugen, P. (Pamela) <Pamela.Rugen@akzonobel.com>
Sent: Wednesday, May 16, 2018 8:25 AM
To: Odusote, Gloria
Subject: RE: Concerning your case

Hi Gloria,
Yes thank you.
Pam

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Tuesday, May 15, 2018 5:11 PM
To: Rugen, P. (Pamela)
Subject: RE: Concerning your case

Hi Pam,
Your Day 90 is coming up. Should I continue to suspend until you provide new data?

Best,
Gloria

From: Rugen, P. (Pamela) [mailto:Pamela.Rugen@akzonobel.com]
Sent: Thursday, April 19, 2018 9:22 PM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: [DMARC Fail] RE: Concerning your case

Hi Gloria,
Yes, thank you.
Pam

From: Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]
Sent: Thursday, April 19, 2018 4:52 PM
To: Rugen, P. (Pamela)
Subject: Concerning your case

Hi Pam,
I completely forgot to mention suspensions during our last phone call. Would you like to request one? Your Day 90 is tomorrow.

Best,
Gloria

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Odusote, Gloria

From: Rugen, P. (Pamela) <Pamela.Rugen@akzonobel.com>
Sent: Tuesday, April 17, 2018 3:09 PM
To: Odusote, Gloria
Subject: RE: Respiratory sensitization

Ok, we are calling in now.

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Tuesday, April 17, 2018 2:08 PM
To: Rugen, P. (Pamela)
Subject: RE: Respiratory sensitization

Hi Pam,
There seems to be something wrong with the call in number

Can you call this number [REDACTED]
[REDACTED]

From: Rugen, P. (Pamela) [mailto:Pamela.Rugen@akzonobel.com]
Sent: Monday, April 16, 2018 1:02 PM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: Rugen, P. (Pamela) <Pamela.Rugen@akzonobel.com>
Subject: FW: Respiratory sensitization

Hi Gloria,
[REDACTED] and I look forward to speaking with your team tomorrow.
This is just to confirm that [REDACTED] can make the meeting.
Pam

From: [REDACTED]
Sent: Sunday, April 15, 2018 11:28 AM
To: Rugen, P. (Pamela)
Subject: Re: Respiratory sensitization

Happy Sunday. Yes I can attend the call. [REDACTED]

Sent from my iPhone

On Apr 15, 2018, at 11:17 AM, Rugen, P. (Pamela) <Pamela.Rugen@akzonobel.com> wrote:

Hi Ed,
Please confirm that you are available to attend the meeting with EPA on Tuesday at 3:00 p.m. (eastern time).

The Conference number is [REDACTED].

Thank you,
Pam

From: Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]

Sent: Friday, April 13, 2018 2:36 PM

To: Rugen, P. (Pamela)

Subject: RE: Respiratory sensitization

Hi Pam,

They've both accepted for Tuesday at 3pm. The conference number is the same as what was listed below. Please let me know if that works for [REDACTED]

Best,
Gloria

From: Odusote, Gloria

Sent: Friday, April 13, 2018 3:25 PM

To: 'Rugen, P. (Pamela)' <Pamela.Rugen@akzonobel.com>

Subject: RE: Respiratory sensitization

Hi Pam,

The Conference number is [REDACTED].

Unfortunately, I was just told that Monday would not work for one of the assessors. He said Tuesday the same time will work but I'll know for sure Monday morning.

Best,
Gloria

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]

Sent: Friday, April 13, 2018 3:14 PM

To: Odusote, Gloria <odusote.gloria@epa.gov>

Subject: RE: Respiratory sensitization

Hi Gloria,

Please send me the call-in information for the meeting on Monday the 16th of April at 3:00 p.m. eastern time.

Thank you and have a nice weekend.

Pam

From: Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]

Sent: Wednesday, April 11, 2018 9:30 AM

To: Rugen, P. (Pamela)

Subject: RE: Respiratory sensitization

Hi Pam,

The toxicologists are free next week Monday at 3pm to have a conference call. Why don't we start there and then if we need to have a face to face meeting in May, we can arrange it then.

Best,
Gloria

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]

Sent: Wednesday, April 11, 2018 9:49 AM

To: Odusote, Gloria <odusote.gloria@epa.gov>

Subject: RE: Respiratory sensitization

Hi Gloria,

We would like to have a face to face meeting with the appropriate personnel concerning the respiratory sensitization issue. [REDACTED] is going to be in D.C. for the OPPSD meeting and would like to arrange a meeting with the EPA Toxicologist(s) on either May 16th or the 18th.

Please let me know if this is possible and confirm the time and place.

Thank you in advance for your assistance.

Pam

Pamela Rugen

Product Regulatory Specialist

Product Stewardship & Regulatory Affairs

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M [REDACTED]

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Chicago, IL 60607



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<image002.gif><image003.gif> 

From: Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]

Sent: Tuesday, April 10, 2018 9:45 AM

To: Rugen, P. (Pamela)

Subject: RE: Respiratory sensitization

Thanks Pam

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]

Sent: Monday, April 9, 2018 8:33 AM

To: Odusote, Gloria <odusote.gloria@epa.gov>

Cc: [REDACTED] >

Subject: RE: Respiratory sensitization

Hello Gloria,

Please consider this email approval to suspend the timeline.

Pam

From: [REDACTED]
Sent: Friday, April 6, 2018 8:56 AM
To: Odusote, Gloria
Cc: Rugen, P. (Pamela)
Subject: Respiratory sensitization

Hello Gloria:

Pam Rugen is our regulatory contact and so please discuss the PMN suspension with her directly.

Regarding the toxicology issue and respiratory sensitization, I reviewed the response from EPA and I did not see comments on the multiple literature references and scientific opinions that I summarized in our paper. I am still completely puzzled as what scientific basis EPA is relying on to include respiratory sensitization in this PMN discussion. I really need to have a sit-down meeting with the EPA toxicology group to discuss this issue. Can you arrange this meeting or should I contact Tala Henry directly?

Regards,

[REDACTED]

[REDACTED]

T [REDACTED]
E [REDACTED]

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Chicago, IL 60607-3835 USA

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Odusote, Gloria

From: Rugen, P. (Pamela) <Pamela.Rugen@akzonobel.com>
Sent: Wednesday, April 11, 2018 11:07 AM
To: Odusote, Gloria
Subject: RE: Respiratory sensitization

Hi Gloria,
I will check with [REDACTED] and hopefully this time will work.
Thank you for the quick reply.
Pam

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Wednesday, April 11, 2018 9:30 AM
To: Rugen, P. (Pamela)
Subject: RE: Respiratory sensitization

Hi Pam,
The toxicologists are free next week Monday at 3pm to have a conference call. Why don't we start there and then if we need to have a face to face meeting in May, we can arrange it then.

Best,
Gloria

From: Rugen, P. (Pamela) [mailto:Pamela.Rugen@akzonobel.com]
Sent: Wednesday, April 11, 2018 9:49 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Respiratory sensitization

Hi Gloria,
We would like to have a face to face meeting with the appropriate personnel concerning the respiratory sensitization issue. [REDACTED] is going to be in D.C. for the OPPSD meeting and would like to arrange a meeting with the EPA Toxicologist(s) on either May 16th or the 18th.
Please let me know if this is possible and confirm the time and place.
Thank you in advance for your assistance.
Pam

Pamela Rugen
Product Regulatory Specialist
Product Stewardship & Regulatory Affairs
Specialty Chemicals

T [REDACTED]
M [REDACTED]
E pamela.rugen@akzonobel.com

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Chicago, IL 60607



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From: Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]
Sent: Tuesday, April 10, 2018 9:45 AM
To: Rugen, P. (Pamela)
Subject: RE: Respiratory sensitization

Thanks Pam

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]
Sent: Monday, April 9, 2018 8:33 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: [REDACTED]
Subject: RE: Respiratory sensitization

Hello Gloria,
Please consider this email approval to suspend the timeline.
Pam

From: [REDACTED]
Sent: Friday, April 6, 2018 8:56 AM
To: Odusote, Gloria
Cc: Rugen, P. (Pamela)
Subject: Respiratory sensitization

Hello Gloria:

Pam Rugen is our regulatory contact and so please discuss the PMN suspension with her directly.

Regarding the toxicology issue and respiratory sensitization, I reviewed the response from EPA and I did not see comments on the multiple literature references and scientific opinions that I summarized in our paper. I am still completely puzzled as what scientific basis EPA is relying on to include respiratory sensitization in this PMN discussion. I really need to have a sit-down meeting with the EPA toxicology group to discuss this issue. Can you arrange this meeting or should I contact Tala Henry directly?

Regards,

[REDACTED]

T

E

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Odusote, Gloria

From: Rugen, P. (Pamela) <Pamela.Rugen@akzonobel.com>
Sent: Wednesday, March 21, 2018 12:23 PM
To: Odusote, Gloria
Subject: RE: EPA Meeting to Discuss PPE

Hi Gloria,
Just checking to see if we are on for today or should we pick another time?
Thanks,
Pam

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Tuesday, March 20, 2018 5:30 PM
To: Rugen, P. (Pamela)
Subject: RE: EPA Meeting to Discuss PPE

Hi Pam,
Your Day 90 is tomorrow, so I will suspend 15 days. Let me know if you have any questions. One toxicologist said he's free. I'm just waiting on the other.

Best,
Gloria

From: Odusote, Gloria
Sent: Tuesday, March 20, 2018 5:12 PM
To: 'Rugen, P. (Pamela)' <Pamela.Rugen@akzonobel.com>
Subject: RE: EPA Meeting to Discuss PPE

Hi Pam,
I will let you know tomorrow. I'm not sure whether the snow tomorrow will be an issue.

Best,
Gloria

From: Rugen, P. (Pamela) [mailto:Pamela.Rugen@akzonobel.com]
Sent: Tuesday, March 20, 2018 5:02 PM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: EPA Meeting to Discuss PPE

Hi Gloria,
Our Senior Toxicologist is committed until 2:30 Wednesday (Chicago time).
Could we meet at 2:30 central time which is 3:30 eastern time?
If so, please pass on the call-in information and I will talk to you then.
Thank you,
Pam

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Monday, March 19, 2018 3:25 PM
To: Rugen, P. (Pamela)
Subject: RE: Face to Face Meeting

Hi Pam,
I completely understand. Will Wednesday at 3pm work?

Best,
Gloria

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]
Sent: Monday, March 19, 2018 10:06 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Face to Face Meeting

Hi Gloria,
Thank you. I know these meetings are difficult to arrange but with our company actually going through a sale, people are being pulled into high level meeting at the drop of a hat.
Thank you again. If this could happen later this week, we would really appreciate it.
Pam

From: Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]
Sent: Monday, March 19, 2018 9:05 AM
To: Rugen, P. (Pamela)
Subject: RE: Face to Face Meeting

Hi Pam,
I will let you know when I hear back from them.

Best,
Gloria

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]
Sent: Monday, March 19, 2018 9:58 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Face to Face Meeting

Hi Gloria,
Should [REDACTED] and I get on the call?
Pam

From: Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]
Sent: Monday, March 19, 2018 8:43 AM
To: Rugen, P. (Pamela)
Subject: RE: Face to Face Meeting

Hi Pam,
Sorry I am trying to track down both toxicologists. I will let you know as soon as I can.

Best,
Gloria

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]
Sent: Monday, March 19, 2018 9:30 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>

Cc: Rugen, P. (Pamela) <Pamela.Rugen@akzonobel.com>

Subject: RE: Face to Face Meeting

Importance: High

Hi Gloria,

[REDACTED] just got back from a European business trip and wondered if this meeting could occur later this week. If that is not possible, we will get on at 9:00 central time.

Please let me know.

Pam

From: Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]

Sent: Monday, March 19, 2018 7:53 AM

To: Rugen, P. (Pamela)

Subject: RE: Face to Face Meeting

Hi Pam,

I forgot to add the conference ID: [REDACTED]

Best,
Gloria

From: Odusote, Gloria

Sent: Monday, March 19, 2018 8:52 AM

To: 'Rugen, P. (Pamela)' <Pamela.Rugen@akzonobel.com>

Subject: RE: Face to Face Meeting

Hi Pam,

Sure, the conference call number will be [REDACTED].

Best,
Gloria

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]

Sent: Friday, March 16, 2018 4:54 PM

To: Odusote, Gloria <odusote.gloria@epa.gov>

Subject: RE: Face to Face Meeting

Hi Gloria,

I believe that our toxicologist really wanted a discussion prior to anything being put on paper by the EPA.

This was what we were looking for and I would think that would be possible.

Thanks,

Pam

From: Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]

Sent: Friday, March 16, 2018 3:52 PM

To: Rugen, P. (Pamela)

Subject: RE: Face to Face Meeting

Hi Pam,

There was a bit of a misunderstanding on my part and we still don't have the response ready to go out. Apparently, the toxicologist I was trying to track down for the final QC was at the SOT meeting. I think it may be best to delay until we can have the written response ready for you to review. I will try to call you back as early as I can on Monday.

I really do understand that you want to have the meeting soon so you can have your chemical on the market as soon as possible and I will try as hard as I can to move the QC process through next week. Thank you so much for your patience.
Best,
Gloria

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]
Sent: Wednesday, March 7, 2018 9:29 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: Rugen, P. (Pamela) <Pamela.Rugen@akzonobel.com>
Subject: Face to Face Meeting

Hi Gloria,
[REDACTED] just informed me he is available for the meeting on the 19th and wondered if it was possible to have a face to face meeting with EPA? I know years ago EPA was open to face to face meetings but with the increase of workloads now, I wasn't sure what the policy was.
Please advise.
Regards,
Pam

Pamela Rugen
Product Regulatory Specialist
Product Stewardship & Regulatory Affairs
Specialty Chemicals

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Odusote, Gloria

From: Odusote, Gloria
Sent: Monday, March 19, 2018 9:59 AM
To: Rugen, P. (Pamela)
Subject: RE: Face to Face Meeting

Hi Pam,
Nope just talked to both and they are fine rescheduling. I am looking at their calendars now.

Best,
Gloria

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]
Sent: Monday, March 19, 2018 9:58 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Face to Face Meeting

Hi Gloria,
Should [REDACTED] and I get on the call?
Pam

From: Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]
Sent: Monday, March 19, 2018 8:43 AM
To: Rugen, P. (Pamela)
Subject: RE: Face to Face Meeting

Hi Pam,
Sorry I am trying to track down both toxicologists. I will let you know as soon as I can.

Best,
Gloria

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]
Sent: Monday, March 19, 2018 9:30 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: Rugen, P. (Pamela) <Pamela.Rugen@akzonobel.com>
Subject: RE: Face to Face Meeting
Importance: High

Hi Gloria,
[REDACTED] just got back from a European business trip and wondered if this meeting could occur later this week.
If that is not possible, we will get on at 9:00 central time.
Please let me know.
Pam

From: Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]
Sent: Monday, March 19, 2018 7:53 AM
To: Rugen, P. (Pamela)
Subject: RE: Face to Face Meeting

Hi Pam,
I forgot to add the conference ID: [REDACTED]

Best,
Gloria

From: Odusote, Gloria
Sent: Monday, March 19, 2018 8:52 AM
To: 'Rugen, P. (Pamela)' <Pamela.Rugen@akzonobel.com>
Subject: RE: Face to Face Meeting

Hi Pam,
Sure, the conference call number will be [REDACTED].

Best,
Gloria

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]
Sent: Friday, March 16, 2018 4:54 PM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Face to Face Meeting

Hi Gloria,
I believe that our toxicologist really wanted a discussion prior to anything being put on paper by the EPA. This was what we were looking for and I would think that would be possible.
Thanks,
Pam

From: Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]
Sent: Friday, March 16, 2018 3:52 PM
To: Rugen, P. (Pamela)
Subject: RE: Face to Face Meeting

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I really do understand that you want to have the meeting soon so you can have your chemical on the market as soon as possible and I will try as hard as I can to move the QC process through next week. Thank you so much for your patience.
Best,
Gloria

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]
Sent: Wednesday, March 7, 2018 9:29 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: Rugen, P. (Pamela) <Pamela.Rugen@akzonobel.com>
Subject: Face to Face Meeting

Hi Gloria,

[REDACTED] just informed me he is available for the meeting on the 19th and wondered if it was possible to have a face to face meeting with EPA? I know years ago EPA was open to face to face meetings but with the increase of workloads now, I wasn't sure what the policy was.

Please advise.

Regards,

Pam

Pamela Rugen

Product Regulatory Specialist

Product Stewardship & Regulatory Affairs

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Odusote, Gloria

From: Rugen, P. (Pamela) <Pamela.Rugen@akzonobel.com>
Sent: Friday, March 2, 2018 9:29 AM
To: Odusote, Gloria
Subject: FW: Status of Review - Butanox P-50

Hi Gloria,

The week of the 12th does not work as I am at the Society of Toxicology meeting and the key toxicologist that needs to be on the call will be in Europe. I think at this point we would like to meet with the toxicologists as I doubt medical monitoring at our customer's sites would be feasible.

Please set up a meeting either the week of March 19th or the week of March 26th.

Thank you,

Pam

From: Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]
Sent: Thursday, March 1, 2018 3:11 PM
To: Rugen, P. (Pamela)
Subject: RE: Status of Review - Butanox P-50

Hey Pam,

Thanks for the response. I was also wondering if medical monitoring would be a possibility for your chemical if I brought the issue up to the Office Director. I am not sure we can say with confidence that this is not a respiratory sensitizer but I wanted to present a new possibility to the Office Director instead of the usual APF 1000. If I made the case that we could try medical monitoring for your case instead of the APF 1000, is that something feasible for your PMN?

Would the week of the 12th work for a meeting? I should be sending our written response next week. I will preface the meeting by stating that while it is hard to prove the negative in toxicology, if you have any other scientific references to support the fact that peroxides are not respiratory sensitizers, that would be very helpful.

Best,
Gloria

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]
Sent: Wednesday, February 28, 2018 11:21 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: Rugen, P. (Pamela) <Pamela.Rugen@akzonobel.com>
Subject: FW: Status of Review - Butanox P-50

Hi Gloria,

I hope this finds you well. I wanted to get back to you as I am not sure we are able to get any medical surveillance information as the system in the EU is completely closed. Please let us know when we can meet with your toxicologists as we would like to discuss the respiratory sensitization information that we sent on August 10th.

Thank you,
Pam

From: Rugen, P. (Pamela)
Sent: Thursday, February 1, 2018 9:30 AM
To: Gloria Odusote (odusote.gloria@epa.gov)
Cc: Rugen, P. (Pamela)
Subject: FW: Status of Review - Butanox P-50

Hi Gloria,
Please let me know the status of the EPA review and I believe we are past the extension date.
You have approval from me to extend this for another 15 days.
Thank you,
Pam

From: Rugen, P. (Pamela)
Sent: Thursday, January 25, 2018 8:15 AM
To: Gloria Odusote (odusote.gloria@epa.gov)
Cc: Rugen, P. (Pamela)
Subject: FW: Status of Review - Butanox P-50

Hi Gloria,
I have a team meeting coming up this afternoon and wondered if you could give me an update on the status of the EPA review.
Thank you,
Pam

From: Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]
Sent: Wednesday, January 10, 2018 6:16 PM
To: Rugen, P. (Pamela)
Subject: RE: Status of Review

Hi Pam,
I am sorry for the delay. I drafted part of the response to your questions and I am trying to put it up the chain of my management. I will let you know if anything major happens.

I am pushing to have a meeting with RAD the week after next. After that, we can schedule the meeting between RAD and the toxicologists at AkzoNobel.

Best,
Gloria

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]
Sent: Tuesday, January 9, 2018 9:29 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: Rugen, P. (Pamela) <Pamela.Rugen@akzonobel.com>
Subject: Status of Review

Hi Gloria,
Happy New Year to you. I travelled east and back from Wisconsin and the weather was great for traveling over the holidays, thank goodness. I think the east has gotten more snow than we have which is odd. We have had that arctic blast of cold weather though.
Please let me know if there is any change in the status of this review.
Pam

Pamela Rugen
Toxicologist/Product Regulatory Specialist
Regulatory Affairs

T [REDACTED]
M [REDACTED]
E pamela.rugen@akzonobel.com

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Odusote, Gloria

From: Rugen, P. (Pamela) <Pamela.Rugen@akzonobel.com>
Sent: Wednesday, February 21, 2018 4:58 PM
To: Odusote, Gloria
Cc: Rugen, P. (Pamela)
Subject: RE: Medical Monitoring Data

Hi Gloria,

Sorry it has taken me so long in getting back to you but several key people have been traveling a lot recently and have been difficult to catch up with. It looks like we might have occupational health data on a similar product that we sell from our EU plant but not specifically the Bx P50.

When I get additional information about the details I will pass it onto you.

Pam

From: Rugen, P. (Pamela)
Sent: Wednesday, February 7, 2018 5:50 PM
To: Gloria Odusote (odusote.gloria@epa.gov)
Cc: Rugen, P. (Pamela)
Subject: Medical Monitoring Data

Hi Gloria,

I received your vm and am looking into the monitoring data. I have never attempted to get industrial hygiene type data in this company but will let you know.

Thanks,

Pam

Pamela Rugen
Product Regulatory Specialist
Product Stewardship & Regulatory Affairs
Specialty Chemicals

T [REDACTED]
M [REDACTED]
E pamela.rugen@akzonobel.com

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Chicago, IL 60607



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Odusote, Gloria

From: Rugen, P. (Pamela) <Pamela.Rugen@akzonobel.com>
Sent: Thursday, January 25, 2018 2:09 PM
To: Odusote, Gloria
Subject: RE: Status of Review - Butanox P-50

Hi Gloria,
I have a late afternoon appointment, so tomorrow would be fine.
Thank you,
Pam

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Thursday, January 25, 2018 1:05 PM
To: Rugen, P. (Pamela)
Subject: RE: Status of Review - Butanox P-50

Hi Pam,
I am in a weeklong conference and am not in touch with the other people in on the review. I'm coming back to the office at 5:30 and can look stuff up then if you're free.

Best,
Gloria

From: Rugen, P. (Pamela) [mailto:Pamela.Rugen@akzonobel.com]
Sent: Thursday, January 25, 2018 9:15 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: Rugen, P. (Pamela) <Pamela.Rugen@akzonobel.com>
Subject: FW: Status of Review - Butanox P-50

Hi Gloria,
I have a team meeting coming up this afternoon and wondered if you could give me an update on the status of the EPA review.
Thank you,
Pam

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Wednesday, January 10, 2018 6:16 PM
To: Rugen, P. (Pamela)
Subject: RE: Status of Review

Hi Pam,
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I am pushing to have a meeting with RAD the week after next. After that, we can schedule the meeting between RAD and the toxicologists at AkzoNobel.

Best,
Gloria

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]
Sent: Tuesday, January 9, 2018 9:29 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: Rugen, P. (Pamela) <Pamela.Rugen@akzonobel.com>
Subject: Status of Review

Hi Gloria,

Happy New Year to you. I travelled east and back from Wisconsin and the weather was great for traveling over the holidays, thank goodness. I think the east has gotten more snow than we have which is odd. We have had that arctic blast of cold weather though.

Please let me know if there is any change in the status of this review.

Pam

Pamela Rugen

Toxicologist/Product Regulatory Specialist
Regulatory Affairs

T [REDACTED]
M [REDACTED]
E pamela.rugen@akzonobel.com

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Odusote, Gloria

From: Odusote, Gloria
Sent: Thursday, December 28, 2017 3:42 PM
To: Rugen, P. (Pamela)
Subject: RE: Akzo Nobel and EPA Meeting

Yes, definitely. I will try to schedule after the holidays.
Happy New Year!

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]
Sent: Thursday, December 28, 2017 3:37 PM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Akzo Nobel and EPA Meeting

Hi Gloria,
Just a reminder, we would like to have a discussion with EPA concerning this classification if at all possible.
Have a Happy New Year.
Pam

From: Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]
Sent: Thursday, December 28, 2017 1:19 PM
To: Rugen, P. (Pamela)
Subject: RE: Akzo Nobel and EPA Meeting

Hi Pam,
We may have a decision by the scientists by the end of January of whether we will classify this substance as a respiratory sensitizer but the case would have to go through the Office Director, which will take some time. Adding to that, I have no idea whether he will want to regulate as a SNUR/not likely, which would add more time, or as a consent order. Either way, it would be highly unlikely that this case would be completed by the end of January. I will say that this is not specific to your case, all cases are now going to the Office Director.

Best regards,
Gloria

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]
Sent: Thursday, December 28, 2017 2:10 PM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Akzo Nobel and EPA Meeting

Hi Gloria,
Yes, please consider this approval for another extension. I am being asked as to an estimate when a decision will be made though I realize it is a difficult question. Could we say that by the end of January we would have a decision....just wondering.
Hope you have a Happy New Year.
Pam

From: Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]
Sent: Thursday, December 28, 2017 1:04 PM

To: Rugen, P. (Pamela)
Subject: RE: Akzo Nobel and EPA Meeting

Hi Pam,
Your Day 90 is tomorrow, would you like to suspend again? There is no real update except that the case has moved up to the next tier. As I've told you before, this is a major policy shift so there are a lot of hands in the pot, as they say. I will try to keep you as updated as I can. Feel free to call.

Best,
Gloria

From: Odusote, Gloria
Sent: Monday, December 11, 2017 11:03 AM
To: 'Rugen, P. (Pamela)' <Pamela.Rugen@akzonobel.com>
Subject: RE: Akzo Nobel and EPA Meeting

Hi Pam,
Happy Holidays. Your new Day 90 is the 29th.

Best,
Gloria

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]
Sent: Thursday, December 7, 2017 8:19 PM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Akzo Nobel and EPA Meeting

Hi Gloria,
I will be traveling from Wisconsin back to Delaware on the 15th so I will approve another suspension which will take us to the end of the year. Makes it easier for everyone and then we don't have to worry about catching up with each other over the next week. I am encouraged to hear that the assessor was impressed with the document and hopefully it can help to set precedence in the world of peroxides.
Thank you for the update and have a wonderful holiday if we don't communicate between now and the holidays.
Pam

From: Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]
Sent: Thursday, December 7, 2017 7:02 PM
To: Rugen, P. (Pamela)
Subject: RE: Akzo Nobel and EPA Meeting

Hi Pam,
This is the normal route for cases that will have a ripple effect on multiple other cases currently in review. The plus side is the health assessor was very impressed by your document and is excited to go to the Hazard Team and start a comprehensive dialogue about your case.

He is still writing an assessment that other toxicologists will have to read before the meeting, so I will let you know when he is done with that and when the meeting is scheduled.

We are still good from the last suspension until December 14th. Please let me know if you would like another suspension.

Best,

Gloria

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]
Sent: Thursday, December 7, 2017 11:39 AM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Akzo Nobel and EPA Meeting

Hi Gloria,

I know you stated to me that you were hoping to get our rebuttal re-evaluated by the Hazard Team in New Chemicals. I wondered if that was an accepted route for the document to go and would you have any idea as to when we might be contacted with a decision from EPA? Also, when do we have to approve another extension? Thank you and have a nice holiday if we don't speak in a couple of weeks.

Pam

From: Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]
Sent: Friday, October 6, 2017 2:08 PM
To: Rugen, P. (Pamela)
Subject: RE: Akzo Nobel and EPA Meeting

Hi Pam,

Day 90 is coming up, would you like to suspend? I sent you a voicemail as well so let me know if there is anything I can do.

Best,
Gloria

From: Odusote, Gloria
Sent: Wednesday, October 4, 2017 1:42 PM
To: 'Rugen, P. (Pamela)' <Pamela.Rugen@akzonobel.com>
Subject: RE: Akzo Nobel and EPA Meeting

Hi Pam,

Sorry for the delay. Were there specific points in the response you want to discuss? The toxicologist and I worry that without further input, it will be him just reading off the response.

Best,
Gloria

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]
Sent: Monday, October 2, 2017 5:57 PM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: Akzo Nobel and EPA Meeting

Hi Gloria,

We are interested in meeting with the tox team to review the EPA document sent to us concerning respiratory sensitization.

We just want to make sure we are interpreting the comments correctly. We are currently working on gathering additional data and information to submit.

Please let me know when we can organize this meeting.

Thank you,

Pam

Pamela Rugen
Toxicologist/Product Regulatory Specialist
Regulatory Affairs



E pamela.rugen@akzonobel.com

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Odusote, Gloria

From: Odusote, Gloria
Sent: Wednesday, November 29, 2017 1:33 PM
To: Rugen, P. (Pamela)
Subject: RE: Support Document P-17-0294

Hi Pam,

I hope you had a great Thanksgiving holiday. As we discussed the new Day 90 will be December 14th.

I am pushing for this case to be brought to the full hazard team, so I will let you know when that is scheduled. It might take some time as there will be quite a bit of literature review necessary before the meeting.

Best regards,
Gloria Odusote

From: Rugen, P. (Pamela) [mailto:Pamela.Rugen@akzonobel.com]
Sent: Friday, November 10, 2017 5:00 PM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: Support Document P-17-0294

Hi Gloria,

I just wanted to let you know we just submitted a Support Document.

Have a great weekend.

Pam

Pamela Rugen
Toxicologist/Product Regulatory Specialist
Regulatory Affairs



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Odusote, Gloria

From: Rugen, P. (Pamela) <Pamela.Rugen@akzonobel.com>
Sent: Friday, October 6, 2017 3:21 PM
To: Odusote, Gloria
Subject: RE: Akzo Nobel and EPA Meeting

Hi Gloria,

Yes, the 15 day suspension is fine and I have passed on the request for specific questions if we are going to meet with the EPA Toxicologists. We are still gathering information on our side so at the moment I am not being pressured to get a meeting together and I totally understand that EPA in general is swamped with work.

Thank you,

Pam

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Friday, October 6, 2017 2:19 PM
To: Rugen, P. (Pamela)
Subject: RE: Akzo Nobel and EPA Meeting

Hi Pam,

Assuming that you are requesting the 15 day suspension, the new Day 90 is on the 21st of October.

Also as I stated on the voicemail, there has been a lot of pressure on the scientists and the amount of work they have to do on the existing chemicals side is staggering. It's going to take some time to set up a meeting, so if you want to have a meeting, we can arrange that but it might be best to have something he can read beforehand so we don't draw out the process longer than need be.

Best,
Gloria

From: Rugen, P. (Pamela) [mailto:Pamela.Rugen@akzonobel.com]
Sent: Friday, October 6, 2017 3:10 PM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Akzo Nobel and EPA Meeting

Hi Gloria,

Please consider this confirmation to suspend/extend the deadline. Please let me know the new date.

Thank you and have a nice weekend.

Pam

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Friday, October 6, 2017 2:08 PM
To: Rugen, P. (Pamela)
Subject: RE: Akzo Nobel and EPA Meeting

Hi Pam,

Day 90 is coming up, would you like to suspend? I sent you a voicemail as well so let me know if there is anything I can do.

Best,

Gloria

From: Odusote, Gloria
Sent: Wednesday, October 4, 2017 1:42 PM
To: 'Rugen, P. (Pamela)' <Pamela.Rugen@akzonobel.com>
Subject: RE: Akzo Nobel and EPA Meeting

Hi Pam,
Sorry for the delay. Were there specific points in the response you want to discuss? The toxicologist and I worry that without further input, it will be him just reading off the response.

Best,
Gloria

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]
Sent: Monday, October 2, 2017 5:57 PM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: Akzo Nobel and EPA Meeting

Hi Gloria,
We are interested in meeting with the tox team to review the EPA document sent to us concerning respiratory sensitization.
We just want to make sure we are interpreting the comments correctly. We are currently working on gathering additional data and information to submit.
Please let me know when we can organize this meeting.
Thank you,
Pam

Pamela Rugen
Toxicologist/Product Regulatory Specialist
Regulatory Affairs

T [REDACTED]
[REDACTED]

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Odusote, Gloria

From: Rugen, P. (Pamela) <Pamela.Rugen@akzonobel.com>
Sent: Thursday, September 14, 2017 3:31 PM
To: Odusote, Gloria
Subject: RE: Akzo Nobel Fax#

yes please.
Pam

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Thursday, September 14, 2017 2:19 PM
To: Rugen, P. (Pamela)
Subject: RE: Akzo Nobel Fax#

Goodness! Let's hope they listen to you from now on especially since you're the one that interacts with us.

Should I apply a 15 day extension on the case?

Best,
Gloria

From: Rugen, P. (Pamela) [mailto:Pamela.Rugen@akzonobel.com]
Sent: Thursday, September 14, 2017 1:51 PM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: RE: Akzo Nobel Fax#

Hi Gloria,
Thanks so much. I pushed our team to submit a comprehensive lit search with the comments and also go and get the worker exposure data in our plant where a similar peroxide is used but I did not have a big enough voice.
I will be in touch.
Pam

From: Odusote, Gloria [mailto:odusote.gloria@epa.gov]
Sent: Thursday, September 14, 2017 12:13 PM
To: Rugen, P. (Pamela)
Subject: RE: Akzo Nobel Fax#

Hi Pam,
I sent it exactly at 1pm.

Best,
Gloria

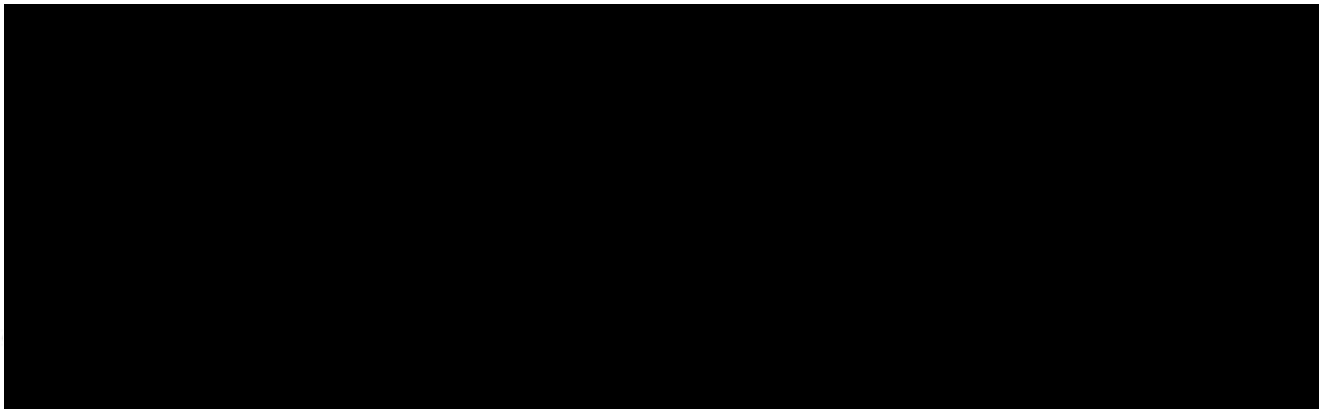
From: Rugen, P. (Pamela) [mailto:Pamela.Rugen@akzonobel.com]
Sent: Thursday, September 14, 2017 12:59 PM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Subject: FW: Akzo Nobel Fax#

Hi Gloria,
Could you shoot me a quick email when you send it?
Thanks,
Pam

From: Rugen, P. (Pamela)
Sent: Thursday, September 14, 2017 11:06 AM
To: Gloria Odusote (odusote.gloria@epa.gov)
Subject: Akzo Nobel Fax#

Hi Gloria,
Please use the same fax# as Kendra did as seen below.
Thank you,
Pam

FAX



Pamela Rugen
Toxicologist/Product Regulatory Specialist
Regulatory Affairs



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Odusote, Gloria

From: Rugen, P. (Pamela) <Pamela.Rugen@akzonobel.com>
Sent: Thursday, September 28, 2017 4:18 PM
To: Odusote, Gloria
Subject: Meeting with EPA

Hi Gloria,

[REDACTED] would like to know if we could have a quick meeting with the lead team member concerning the comments sent back to us on the respiratory sensitization issue. We want to make sure that we are clear as to the position that EPA has taken concerning this issue.

We would like a time at the end of next week if that is possible.

Thank you in advance for your assistance.

Pam

Pamela Rugen
Toxicologist/Product Regulatory Specialist
Regulatory Affairs



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From: Odusote, Gloria [<mailto:odusote.gloria@epa.gov>]
Sent: Wednesday, June 20, 2018 5:02 PM
To: Rugen, P. (Pamela)
Subject: RE: P-17-0294 => Face to Face Meeting Request

Hi Pam,

I put in a 15 day suspension. Would you like to combine the meetings? I talked to Jim Alwood and it seems you will have the meeting with the Director of New Chemicals and the RAD Manager that deals with similar chemicals. It also seems like the same scientists will be there.

Best,
Gloria

From: Rugen, P. (Pamela) [<mailto:Pamela.Rugen@akzonobel.com>]
Sent: Tuesday, June 19, 2018 5:16 PM
To: Odusote, Gloria <odusote.gloria@epa.gov>
Cc: Rugen, P. (Pamela) <Pamela.Rugen@akzonobel.com>
Subject: P-17-0294 => Face to Face Meeting Request

Hi Gloria,

[REDACTED] will be meeting with EPA (concerning another peroxide) during the week of July 16th. He would also like to meet with the Directors of both Risk Assessment and New Chemicals during this time. I wanted to know if that was possible. I also realize that you probably need a formal approval for an extension, so please consider this email that approval.

Thank you as always,
Pam

Pamela Rugen

Senior Product Regulatory Specialist
Product Stewardship & Regulatory Affairs
Specialty Chemicals



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